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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,494	10/03/2003	Randall S. Hickle	82021-0044	4564

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EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
08/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 10/677,494	**Applicant(s)** HICKLE, RANDALL S.
	Examiner KRISTEN C. MATTER	**Art Unit** 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _11 June 2009_.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-20_ is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1-20_ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: _EP 1075848_.

DETAILED ACTION

This Action is in response to the Request for Continued Examination filed 6/11/2009. Claims 1, 13, and 19 have been amended, and no claims haven been added or cancelled. Currently, claims 1-20 are pending in the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6, 7, 12, 13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle (WO 99/62403) in view of Robertson (EP 1075848) and Goldstein (US 6,012,455).

As to claims 1, 2, 6, 7, and 13, Hickle discloses a sedation and analgesia system, comprising a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, pg 23, 1st full paragraph); a drug delivery controller (2a) supplying one or more drugs to the patient; a user interface (16); a gas monitoring and delivery system (2) supplying one or more types of gas to the patient (paragraph 0081); an electronic controller (14) interconnected with the patient health monitor(12a), the user interface(16), gas monitoring and delivery system (2), and drug delivery controller (2a), wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (pg 27, 1st full paragraph).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. However, Robertson discloses a mouthpiece/bite block (figure 8) for the delivery of gases to a user comprising a vestibular shield (2) and a conduit for locating between the wearer's teeth (abstract) capable of delivering gases to the user's oral passage via a central channel 304 that allows access to the mouth. It would be reasonable to one of ordinary skill in the art to use the channel in the mouthpiece of Robertson as a viable alternative to a facemask for passing gas to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Robertson with the system of Hickle so that a user can comfortably and effectively grasp and hold the mouthpiece in place while sedated without an overly intrusive design. Furthermore, the type of interface means is a well known design consideration depending on the specific treatment needed and patient's personal preferences. Based upon the sedation being delivered through the facemask of Hickle and now substituting the bite block taught by Robertson it would have obvious that the electronic controller of Hickle receives said signal and in response to said signal manages the application of the drugs through the bite block (as the bite block is being substituted for the facemask of Hickle and the drugs were previously delivered through the facemask therefore it would be obvious that the drugs would be delivered through the bite block now as one delivery means being substituted for another).

Robertson lacks a means of delivering the drugs and gases to the user's nares. However, Goldstein teaches a mouthpiece with a nasal cannula (figure 14) which is useful as an air delivery apparatus that uses a mouthpiece (92) to stabilize the air delivery apparatus to provide a good air seal. The air delivery apparatus taught by Goldstein uses a nasal cannula that seals in each of the nares of the user and is capable of delivering gases to the user's nares and the said nasal cannula is taught to be attached to a mouthpiece and could be quickly and easily attached to the elbow connector disclosed by Robertson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mouthpiece and air delivery apparatus disclosed by Hickle and Robertson, to utilize a nasal cannula that delivers gas to a users nasal passage as taught by Goldstein in order to provide a gas delivery apparatus that also delivers breathing gas to a users nasal passages because it is "almost universally adopted based on the well known observation that humans show a decided preference for nasal breathing during sleep." See: Robertson [0002]. Additionally, it appears as though the modified device of Hickle would perform equally well with gas being delivered to both the nose and mouth because there is nothing structurally that would prevent such a modification and it is well known that breathing gases are often supplied to both the nose and mouth simultaneously to ensure the desired therapy is being delivered regardless of how a patient is breathing or in case one or the other of the passages becomes occluded.

Regarding claim 12, Robertson discloses the mouthpiece/bite block has a tongue depressor (55) for holding down the patient's tongue and prevent the bite block from being pushed out.

Regarding claim 18, the modified device would have the nasal and oral delivery menas attached to one another, and therefore integrated, so that gases, fluids, and dfrugs can be delivered both nasally and orally.

Claims 3-5, 10, 11, 14-17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle, Robertson, and Goldstein as applied in claims 1, 2, 6, 7, 12, 13, and 18 above and further in view of Kofoed et al. (6,312,389).

As to claims 3 and 14, Hickle and as modified by Robertson and Goldstein disclose the system of claim 2. Robertson discloses a channel (304), but fails to mention that a sensor is located in the channel. Kofoed teaches that a sensor (28) can be located in a channel (40) and have at least one of a sensor (20, 22) and a sampling port (70, 72) connected to the sensor for monitoring gases passing through said at least one channel connected to a nasal cannula for monitoring carbon dioxide of a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bite block of Robertson to employ any well known sensor and sampling port because it would allow a user to monitor the carbon dioxide of a patient.

As to claims 4 and 16, Kofoed further teaches the system wherein said at least one channel is used for at least one or respiratory rate monitoring, oxygen concentration monitoring (carbon dioxide is indicative of an oxygen concentration and therefore meets the limitation of the claim), positive and negative respiratory pressure monitoring, temperature monitoring, humidity monitoring, and respiratory flow monitoring.

As to claim 5, Hickle discloses the system wherein said electronic controller alters said drug delivery based on said patient's conditions as monitored by said sensors (page 18, 1st full paragraph).

As to claim 10, Hickle/Robertson/Goldstein modified by Kofoed combine to disclose (as presented in claim 3) said at least one channel comprising at least one of a sensor of a sensor and sampling port connected to a sensor for monitoring gas output from said gas supply through said at least one channel. Hickle presents in pg 6 into pg 7 last full paragraph, the system monitors inhaled gases which is from said gas supply.

As to claim 11, Hickle discloses (page 18, 1st full paragraph) said electronic controller alters delivery of gas from said supply based on said patient's conditions as monitored by said sensors.

As to claim 15, Kofoed does not teach said sensors are wirelessly integrated with said electronic controller, however such sensors are well known and commonly used in the art. Therefore, it would have been obvious to one of ordinary skill in the art to wirelessly integrate the sensors in order to avoid the need for wires that could tangle, break, or become exposed to the patient.

As to claim 17, the bite block of Robertson includes a tongue depressor (55) as discussed above.

As to claim 19, Hickle discloses a sedation and analgesia system (2). The bite block of Robertson modified by the teachings of Hickle and Goldstein yield a bite block with functionalities that can be integrated with said sedation and analgesia system; Hickle's system provides computer programming capable of comparing patient data and a controller that adjusts the gas delivered to a patient (Hickle pg 16, 1st full paragraph). The method steps would have been obvious because they would have resulted from the use of the device of Hickle/Robertson/Goldstein/Kofoed/. The bite block of Robertson is fully capable of having data being received through the channels of the bite block to the controller of Hickle because there is nothing blocking the flow of data from being transmitted there through.

As to claim 20, Hickle discloses electrical leads (figure 3a, power cord), gas delivery tubes (figure 1, tubes entering facemask), fluid delivery tubes (figure 1, tubes entering face mask). The method steps would have been obvious because they would have resulted from the use of the device of Hickle.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle, Robertson, and Goldstein as applied to claims 1, 2, 6, 7, 12, 13, and 18 above, and further in view of Curti (US 6,533,983).

The modified Hickle device does not disclose the channel being formed so that gas can pass from the nasal cannula to the patient's mouth or that the cannula comprises oral delivery chambers (i.e., Goldstein has a resilient connector 46 or tubes 100). However, Curti discloses that it is well known and commonly used to deliver gases to both the nose and mouth of a patient via a common chambers within the cannula (column 1, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have connected the nasal cannula and oral delivery tube as taught by Curti in the modified Hickle device (via the elbow of Robertson for example) in order to reduce the number of supply tubes running to the patient.

Response to Arguments

Applicant's arguments filed 6/11/2009 have been fully considered but they are moot in view of the new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art cited is to show other breathing devices that deliver air to both the nose and mouth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771